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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,649

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Michael Huenerbein

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EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

10/19/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/538,649

Applicant(s)

HUENERBEIN, MICHAEL

Examiner

Rene Towa

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed May 7, 2007. Claims 1-13 are pending. Claims 1, 5 & 9-11 have been amended. No claim has been cancelled. New claims 12-13 have been added.

Claim Objections

2. Claims 6 & 10-12 are objected to because of the following informalities:

In regards to claim 6, at line 4, the limitation "this" appears to render the claim indefinite; for example, one cannot be certain what "this" is supposed to represent.

In regards to claims 10-11,

at step (b) & (c), "the tissue sample" should apparently read --tissue samples-- as per line 1 of the claim so as to avoid a potential indefiniteness problem; for example, it is unclear whether or not the method pertains to sampling a single or a plurality of tissue samples;

moreover, at step (b), "the lateral opening" should apparently read --the at least one lateral opening-- as per step (a) to avoid a potential indefiniteness problem; for example, it is unclear whether or not the method requires a single or a plurality of lateral openings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 provides for the use of an optical instrument according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. **Claims 1, 4, 6, 8-9 & 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Lifton (US 4,651,753).

In regards to **claim 1**, Lifton discloses an optical biopsy instrument 1, comprising

(a) a substantially cylindrical cannula 1A with a proximal end and a distal end, said cannula 1A having at least one lateral opening 3 in a side surface of said cannula 1A, and

(b) an endoscope (17, 21) which is axially movable inside the cannula 1A and is adapted to separate a tissue sample brought through the lateral opening 3 from the rest of the tissue (see figs. 1-5; col. 1, lines 5-8; col. 3, lines 1-10, 18-23 & 38-58; col. 4, lines 4-23).

In regards to **claim 4**, Lifton discloses an optical biopsy instrument 1 characterized in that the at least one lateral opening 3 has a substantially oval or elliptic configuration (see fig. 2; col. 3, lines 18-23).

In regards to **claim 6**, Lifton discloses an optical biopsy instrument 1 characterized in that an external diameter of the endoscope (17, 21) substantially corresponds to an internal diameter of the cannula 1A or is slightly smaller (see fig. 1).

In regards to **claim 8**, Lifton discloses an optical biopsy instrument 1 characterized in that the endoscope (17, 21) is a rigid endoscope (17, 21) (see fig. 3, lines 38-49).

In regards to **claim 9**, Lifton discloses the use of an optical biopsy instrument 1 for endoscopy (see figs. 3a-f; col. 4, lines 4-23).

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In regards to **claim 13**, Lifton discloses an optical biopsy instrument 1, comprising:

(a) a substantially cylindrical cannula 1A with a proximal end and a distal end, said cannula 1A having at least one lateral opening 3 in a side surface of the cannula 1A, and

(b) an endoscope (17, 21) which is axially movable inside the cannula 1A, wherein a clearance formed between the cannula 1A and the endoscope (17, 21) is selected such that a separation of a tissue is enabled by relatively moving at least one of the cannula 1A and the endoscope (17, 21) against each other (see figs. 1-5; col. 1, lines 5-8; col. 3, lines 1-10, 18-23 & 38-58; col. 4, lines 4-23)...

9. **Claims 1-2, 6, 8-9, 10 & 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Boebel (US 4,620,547).

In regards to **claim 1**, Boebel discloses an optical biopsy instrument, comprising

(a) a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and

(b) an endoscope 5 which is axially movable inside the cannula 1 and is adapted to separate a tissue sample brought through the lateral opening 2 from the rest of the tissue (see figs. 1-3; col. 1, lines 7-15; col. 2, lines 18-34, 38-43 & 50-66).

In regards to **claim 2**, Boebel discloses an optical biopsy instrument characterized in that the at least one lateral opening 2 of the cannula 1 has at least in

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parts a cutting region 3 at its area being directed towards the proximal end (see fig. 2; col. 2, lines 18-34).

In regards to **claim 6**, Boebel discloses an optical biopsy instrument characterized in that an external diameter of the endoscope 5 (i.e. the diameter of cutter 6 of endoscope 5) substantially corresponds to an internal diameter of the cannula 1 (see fig. 2).

In regards to **claim 8**, Boebel discloses an optical instrument characterized in that the endoscope 5 is a rigid endoscope 5 (see fig. 2).

In regards to **claim 9**, Boebel discloses the use of an optical biopsy instrument for endoscopy (see col. 2, lines 50-66).

In regards to **claim 10**, Boebel discloses a method for sampling tissue samples in duct systems (i.e. the uterus) wherein

(a) an optical biopsy instrument, comprising
-a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and

-an endoscope 5 which is axially movable inside the cannula 1 is introduced, under endoscopic monitoring, into the duct up to a biopsy site,

(b) the tissue samples are brought through the at least one lateral opening 2 into the interior of the cannula 1, and

(c) the tissue samples are separated from the rest of the tissue by retracting the endoscope 5 until the at least one lateral opening 2 is closed (see figs. 1-3; col. 1, lines 7-15; col. 2, lines 18-34, 38-43 & 50-68; col. 3, lines 1-6).

In regards to **claim 13**, Boebel discloses an optical biopsy instrument comprising:

(a) a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of the cannula 1, and

(b) an endoscope 5 which is axially movable inside the cannula 1 wherein a clearance formed between the cannula 1 and the endoscope 5 is selected such that a separation of a tissue sample from a tissue is enabled by relatively moving at least one of the cannula 1 and the endoscope 5 against each other (see figs. 1-3; col. 1, lines 7-15; col. 2, lines 18-34, 38-43 & 50-66).

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Hayafuji et al. (US 5,106,364).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach a cutting region formed by a ground.

However, Hayafuji et al. disclose a biopsy instrument comprising at least one substantially rectangular lateral opening 18; wherein the at least one lateral opening 18

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includes a cutting region 41 formed by a ground edge of the at least one lateral opening 18 (see figs. 2-4; col. 5, lines 20-29 & 51-64; col. 6, lines 18-34 & 51-62).

Since both Boebel and Hayafuji et al. teach biopsy devices for cutting tissue wherein a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action (see abstracts), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Boebel with a ground edge cutting region similar to that of Hayafuji et al. in order to cut tissue such that a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action.

12. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Lifton ('753).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach that the at least lateral opening that is round, oval, elliptic or rectangular in configuration.

However, Lifton discloses a biopsy instrument characterized in that the at least one lateral opening has a substantially oval or elliptic configuration (see fig. 2; col. 3, lines 18-23).

Since both Boebel and Lifton disclose biopsy instruments comprising lateral opening on a side surface thereof to collect severed biopsy samples into a cavity of the instrument, it would have been obvious to one ordinary skill in the art at the time

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Applicant's invention was made to provide an instrument similar to that of Boebel with an oval lateral opening similar to that of Lifton since such a modification would amount to an obvious design choice that would serve the same purpose of collecting severed biopsy samples into a cavity of the instrument.

13. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Yoon (US 4,254,762).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach a transparent distal end wall.

However, Yoon discloses an optical biopsy instrument comprising a transparent distal end wall for forward viewing (see fig. 7; col. 3, lines 58-65; col. 5, lines 41-46; col. 6, lines 43-49 & 55-58).

Since both Boebel and Yoon teach optical biopsy instruments comprising optical system for viewing the tissue region to be biopsied, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Boebel with a transparent end wall similar to that of Yoon in order to observe the tissue region to be biopsied via either one of forward or lateral viewing.

14. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Gatto (US 2003/0181823).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach a cannula diameter of at most 1.2 mm.

Gatto discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most (see par 0036).

Since both Boebel and Gatto disclose optical biopsy instruments for use in duct systems, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Boebel with a cannula external diameter of at most 1.2 mm similar to that of Gatto in order to provide the instrument with the ability to traverse the narrow diameter of the breast ducts (see Gatto, par 0009).

15. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Wang (US 4,702,260).

Boebel discloses a method, as described above in claim 10, that fails to explicitly teach that the tissue is separated by moving a cannula together with a fixed endoscope forward or backward.

However, Wang discloses a biopsy method wherein the tissue is separated by moving a cannula together with a fixed inner cutting element forward or backward to sever tissue (see figs. 2 & 4; col. 4, lines 18-40).

Since Boebel and Wang teach biopsy instruments wherein the outer cannula is capable of separating tissue moving a cannula together with a fixed inner cutting element forward or backward to sever tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Boebel with a step of separating the tissue by moving the cannula

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similar to that of Wang since such a modification would serve the same purpose of severing the tissue.

16. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Berman et al. (US 6,217,598).

Boebel discloses a method, as described above in claim 10, that fails to explicitly teach a lateral opening with cutting teeth.

However, Berman et al. disclose a biopsy instrument comprising an outer cannula comprising a lateral opening with cutting teeth (218, 220) (see fig. 22; col. 6, lines 64-67; col. 7, lines 1-18).

Since both Boebel and Berman et al. teach biopsy devices comprising outer and inner cutting members, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Boebel with cutting teeth similar to that of Berman et al. in order facilitate tissue cutting by spreading a cut from multiple points of initial puncture (i.e. via the teeth).

17. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over in Lifton ('753) view of Gatto ('823).

Lifton discloses a method for sampling tissue samples wherein

(a) a biopsy instrument 1, comprising

-a substantially cylindrical cannula 1A with a proximal end and a distal end, said cannula 1A having at least one lateral opening 3 in a side surface of said cannula 1A, and

-an endoscope (17, 21) which is axially movable inside the cannula 1A is introduced, to a biopsy site,

(b) the tissue samples are brought through the at least one lateral opening 3 into the interior of the cannula 1A, and

(c) the tissue samples are separated from the rest of the tissue by retracting the endoscope (17, 21) until the at least one lateral opening 3 is closed (see figs. 1-5; col. 1, lines 5-8; col. 3, lines 1-10, 18-23 & 38-58; col. 4, lines 4-23).

Lifton discloses a method, as described above, that fails to explicitly teach sampling tissue samples in duct systems or an optical instrument 1.

However, Gatto discloses an optical biopsy instrument and method for sampling tissue samples in duct systems (see par 0035-0036, 0038-0039, 0042 & 0045).

Since both Lifton and Gatto disclose biopsy systems for sampling tissue samples in a patient's body cavity, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Lifton for sampling tissue samples in duct systems similar to that of Gatto in order to sample tissue samples from the duct systems. Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a biopsy method similar to that of Lifton to include an optical instrument similar to that of Gatto in order to view the interior of the duct and identify an area of interest as the endoscope passes on its way through the duct to the area of interest (see Gatto, par 0045).

18. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over in Lifton ('753) in view of Gatto ('823) further in view of Wang ('260).

Lifton as modified by Gatto discloses a method for sampling tissue samples in duct systems, as described above in claim 10, that fails to explicitly teach separating the tissue samples from the rest of the tissue by moving the cannula.

Since Boebel and Wang teach biopsy instruments and methods wherein the outer cannula is capable of separating tissue moving a cannula together with a fixed inner cutting element forward or backward to sever tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Boebel as modified by Gatto, above, with a step of separating the tissue by moving the cannula similar to that of Wang since such a modification would serve the same purpose of severing the tissue.

Response to Arguments

19. Applicant's arguments filed May 7, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

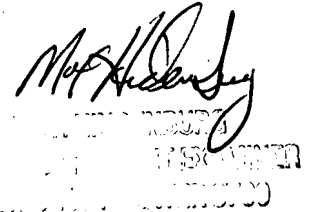
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/RTT/

A handwritten signature in black ink is written over a rectangular official stamp. The signature appears to be "M. H. [unclear]". The stamp contains the text "UNITED STATES PATENT AND TRADEMARK OFFICE" and "WASHINGTON, DC 20590" in a grid-like format.